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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,085	11/06/2001	Todd K. Whitehurst	AB-145U	7482
23845	7590	07/02/2004	EXAMINER	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			MACHUGA, JOSEPH S	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/993,085	Applicant(s) WHITEHURST, TODD K. 8	
	Examiner Joseph S. Machuga	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/25/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 15-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 15-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

The terminal disclaimer filed is sufficient to overcome the provisional double patenting rejection presented in the previous office action.

Applicants arguments are considered moot given the new grounds of rejection.

Applicant is invited to contact the examiner at the number to discuss this case if it will assist in expediting the application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 15-18, 20, 22 and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise #5782798 in view of Fischell #6006124 and either Boveja #6269270 or Terry, Jr. et al #5540730.

3. Rise discloses a method and apparatus for treating obesity. The device includes 2 system control units (100, 16), electrodes (38, 40) and an implantable pump. The system delivers electrical stimulation and therapeutic dosages of one or more drugs to the lateral hypothalamus; paraventricular nucleus or the ventral medial hypothalamus

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(column 3, lines 12+; column 5, lines 19+.) The reference also notes (Table IV) that low frequency pulses (below 100hz) and high frequency pulses (above 100hz) can activate portions of the brain. Not disclosed by this reference is the step of implanting the control system in the skull or brain of the patient to apply a stimulating pulse to the nucleus of the solitary tract or the dorsal motor nucleus of the vagus nerve.

4. Boveja discloses an implantable neural stimulator. The reference teaches (Fig 1a) that the Nucleus of the Solitary tract has direct control over the hypothalamus. Terry, Jr. et al teaches that the stimulation of the dorsal motor nucleus of the vagus nerve provides treatment for patients with diabetes or metabolic disorders. (note specifically column 3, lines 13-30 and column 2, lines 3-11.)

Fischell discloses a deep brain electrode. The reference teaches that the control module can be implanted directly into the skull of the patient. This eliminates frequent bending of the wires leading from the control module to the electrodes in the prior art systems.

It would have been obvious to implant the electrodes of Rises device adjacent the Nucleus of the Solitary Tract to control the hypothalamus and the production of insulin given Boleja's teaching or adjacent the dorsal motor nucleus of the vagus nerve to control motility disorders associated with diabetes given Terry, Jr. et al's teaching. To implant the control modules and pump in Rise's device within the skull of the patient to

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prevent bending of the components that could lead to eventual breakage would have been obvious given Fischell's disclosure. Finally, since there is a well-established link between obesity and certain types of diabetes Rise would provide for the limitation of a method for preventing diabetes recited in the preamble. Such a system would provide for the method recited in the claims.

5. Claims 19 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise #5782798 in view of Fischell #6006124 and either Boveja #6269270 or Terry, Jr. et al #5540730 as applied to claim 1 and 22 above, and further in view of Zabara 5540734 and Frankish et al document "Neuropeptide Y, the Hypothalamus and Diabetes: Insight into the Central Control of Metabolism"

Zabara discloses an implant. The reference teaches the concept of providing a closed loop system (column 5, lines 14+) that automatically activates a stimulator in response to circadian cycles and glucose levels. Frankish et al teaches that NPY, serotonin, CCK, catecholamines etc. are indicators of metabolic disorders associated with diabetes.

Given this teaching by Zabara it would have been obvious to add a closed loop feedback system to the device of the proposed combination that is responsive to the time of day or glucose levels to automate the stimulus function. To make the closed loop feedback system of the proposed combination responsive to NPY levels, serotonin,

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CCK, catecholamines or other diabetic/obesity related indicators, antagonists release factors and the like as disclosed by Frankish et al would also have been obvious since they are known markers. Such a system would provide for the method recited in the claims.

6. Claim 21 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise #5782798 in view of Fischell #6006124 and either Boveja #6269270 or Terry, Jr. et al #5540730 as applied to claims 1 and 22 above, and further in view of Schulman et al #5193540.

Schulman et al discloses a micro stimulator that can be implanted within the brain (column 3, 66+.) The device would have the obvious advantage of eliminating wires extending the tissues of the brain.

Given Schulman et al's teaching it would have been obvious to use an implantable micro stimulator in the device of the proposed combination to eliminate the wires extending through tissues in the brain and thus reducing the chances of peripheral damage. Such a system would provide for the method recited in the claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

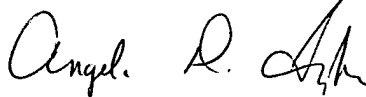
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Joseph S. Machuga
Examiner
Art Unit 3762



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700